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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,744	09/10/2003	Akihiko Miyamoto	031145	3385
38834	7590	03/21/2005	EXAMINER	
WESTERMAN, HATTORI, DANIELS & ADRIAN, LLP 1250 CONNECTICUT AVENUE, NW SUITE 700 WASHINGTON, DC 20036			RAGONESE, ANDREA M	
			ART UNIT	PAPER NUMBER
			3743	

DATE MAILED: 03/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/658,744

Applicant(s)

MIYAMOTO, AKIHIKO

Examiner

Andrea M. Ragonese

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Response to Amendment*

1. The amendment filed on December 22, 2004 has been entered. Examiner acknowledges that **claims 1, 4-7 and 9-11** have been amended. Subsequently, **claims 1 and 3-11** are under consideration.

### *Response to Arguments*

2. Applicant's arguments with respect to **claims 1 and 3-11** have been considered but are moot in view of the new ground(s) of rejection.

### *Claim Rejections - 35 USC § 102*

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. **Claims 1, 3, 4, 7 and 8** are rejected under 35 U.S.C. 102(b) as being anticipated by Kistler (US 4,291,688).

Regarding **claim 1**, Kistler discloses an inhaler **1** comprising: a mouthpiece **4** with at least one air intake opening, and a whistle—as reasonably and broadly interpreted by the Examiner to be the sounding device **18** since the sounding device **18** is fully capable of making a “whistling” sound—attached to said at least one air intake opening provided at a part of the mouthpiece **4** located on an inhalation passage of a finely powdered drug, as shown in Figure 1, wherein the sounding device **18** comprises a partition wall **21**, an air vent **27**, a hollow resonant chamber **23**, and a protrusion **29**,

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and wherein the sounding device **18** makes a sound when the inhalation is done properly (column 3, lines 3-6).

Regarding **claim 3**, as stated in column 5, "The plastic sounding device **18** is easy to insert both mechanically and manually..." and therefore, inherently, the sounding device **18** is removable manually if it can easily be inserted manually. Inherently, when the sounding device **18** is removed, the whistle sound is not made at all.

Regarding **claim 4**, the inhaler **1** further comprises a drug delivery opening for introducing air to take up a finely powdered drug into the delivery passage (column 3, lines 37-44). Additionally, the Examiner notes that Applicant has essentially claimed a statement of intended use. Specifically, Applicant recites, "to correct the difference..." Kistler discloses an inhaler **1** in which the claimed functional limitation can inherently be performed since the inhaler **1** utilizes at least one opening that is *fully capable of* correcting the difference between the lung capacity in the inhalation and the air flow rate in the delivery passage of the finely powdered drug as to prevent breathing difficulty. Applicant is reminded that functional language recitations are statements of intended use utilizing functional language, which may not be given patentable weight in apparatus claims. While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function alone. See MPEP § 2114. Therefore, as broadly interpreted by the Examiner, the previously presented rejection is applied to **claim 4**

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based on the prior art of record. See *In re Swinehart*, 169 USPQ 226 (CCPA 1971); *In re Schreiber*, 44 USPQ2d 1429 (Fed. Cir. 1997).

Regarding **claim 7**, Kistler discloses an inhaler **1** comprising: a drug delivery opening **4** for introducing air to take up a finely powdered drug into a delivery passage, as shown in Figure 1, and an air intake opening to provide air (column 3, lines 37-44), wherein a whistle—as reasonably and broadly interpreted by the Examiner to be the sounding device **18** since the sounding device **18** is fully capable of making a “whistling” sound—as shown in Figure 1, comprises a partition wall **21**, an air vent **27**, a hollow resonant chamber **23**, and a protrusion **29**, wherein said sounding device **18** is attached to said air intake opening, and wherein the sounding device **18** makes a sound when the inhalation is done properly (column 3, lines 3-6). Additionally, the Examiner notes that Applicant has essentially claimed a statement of intended use. Specifically, Applicant recites, “to correct the difference...” Kistler discloses an inhaler **1** in which the claimed functional limitation can inherently be performed since the inhaler **1** utilizes at least one opening that is *fully capable of* correcting the difference between the lung capacity in the inhalation and the air flow rate in the delivery passage of the finely powdered drug as to prevent breathing difficulty. Applicant is reminded that functional language recitations are statements of intended use utilizing functional language, which may not be given patentable weight in apparatus claims. While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function alone. See MPEP § 2114. Therefore, as broadly interpreted by the Examiner,

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the previously presented rejection is applied to **claim 7** based on the prior art of record. See *In re Swinehart*, 169 USPQ 226 (CCPA 1971); *In re Schreiber*, 44 USPQ2d 1429 (Fed. Cir. 1997).

Regarding **claim 8**, as stated in column 5, "The plastic sounding device **18** is easy to insert both mechanically and manually..." and therefore, inherently, the sounding device **18** is removable manually if it can easily be inserted manually. Inherently, when the sounding device **18** is removed, the whistle sound is not made at all.

***Claim Rejections - 35 USC § 102 and 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. **Claims 5, 9 and 10** are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kistler (US 4,291,688). Kistler discloses an inhaler **1** comprising all the limitations recited in **claims 5, 9 and 10**, as applied to **claims 1, 3, 4, 7 and 8** above.

Although Kistler does not explicitly recite that the mouthpiece **4** has two air intake openings, not only would it be within the scope of the invention to have more than one air intake opening to correspond to each of the "one or more channels...provided between the container and the skirt as a path for air to pass into the head-piece and out of the mouth-piece on inhalation," it would be obvious, if not inherent, given the structure shown in Figure 1 and as recited in column 3, lines 37-44. Additionally, the Examiner notes that Applicant has essentially claimed a statement of intended use. Specifically, Applicant recites, "to correct the difference..." Kistler discloses an inhaler **1** in which the claimed functional limitation can inherently be performed since the inhaler **1** utilizes at least one opening that is *fully capable of* correcting the difference between the lung capacity in the inhalation and the air flow rate in the delivery passage of the finely powdered drug as to prevent breathing difficulty. Applicant is reminded that functional language recitations are statements of intended use utilizing functional language, which may not be given patentable weight in apparatus claims. While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function alone. See MPEP § 2114. Therefore, as broadly interpreted by the Examiner, the previously presented rejection is applied to **claims 5, 9 and 10** based on the prior

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art of record. See *In re Swinehart*, 169 USPQ 226 (CCPA 1971); *In re Schreiber*, 44 USPQ2d 1429 (Fed. Cir. 1997).

***Claim Rejections - 35 USC § 103***

8. **Claims 6 and 11** are rejected under 35 U.S.C. 103(a) as being unpatentable over Kistler (US 4,291,688), as applied to **claims 1, 3-5 and 7-10** above, in view of McGavin ("A Modified Aerosol Inhaler For Teaching Techniques"). Kistler discloses an inhaler **1** comprising all the limitations recited in **claims 6 and 11**, with the exception of inserting and removing the sounding device **18** from any of the said air intake openings. However, the use of removable sounding device, or siren, located in an air intake hole on the outside of an inhaler body to notify the user of proper use was known at the time the invention was made. Specifically, McGavin teaches the use of "plastic toy 'siren'" for "patient education" as well as "in the respiratory laboratory." Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the inhaler **1** of Kistler by removing the sounding device **18** and substituting the siren of McGavin because it is well known in the art, as taught by McGavin, to mount a sounding device on the outside of an inhaler body in an air intake opening in order to teach a patient how to properly use the device by emitting "a whizzing noise when air is sucked through it in one direction," indicating proper use of the inhaler device.



***Conclusion***

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Andrea M. Ragonese** whose telephone number is **571-272-4804**. The examiner can normally be reached on Monday through Friday from 9:00 am until 5:00 pm.

11. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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12. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AMR  
March 11, 2005



Henry Bennett  
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